K121159

JUL 20 2012

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone number	(609) 750-2309
Fax number	(609) 275-9445
Establishment Registration Number	3003418325
Name of contact person	Steven R. Peltier, Vice President, Corporate Regulatory Affairs
Date prepared	April 9, 2012
Name of device	
Trade or proprietary name	Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit (for Catheter and Accessories) Integra™ Camino® Flex Adapter (for Adapter and Extension Cable)
Common or usual name	Ventricular Catheter Intracranial Pressure Monitoring System
Classification name	Device, Monitoring, Intracranial Pressure
Classification panel	Neurology
Regulation	Class II, under 21 CFR 882.1620
Product Code(s)	GWM
Legally marketed device(s) to which equivalence is claimed	Ventrix® Ventricular Tunneling Pressure Monitoring Kit (catalog number: NL950-V; formerly known as the OPTYX catheter) 510(k) K904883 Codman® MicroSensor™ Ventricular Catheter Kit 510(k) K991222 Ventricular Pressure Monitoring Kit, Model 110-4HM 510(k) - K914735 Combined Intracranial Pressure-Temperature Sensing System (with pre-amplification cable, catalog number PAC1) 510(k) K962928
Reason for 510(k) submission	New Device

Device description	The Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter functions as an entire system that includes the following: Integra Camino Flex Ventricular Catheter Monitoring Kit (Catheter and Accessories) and Integra Camino Flex Adapter (Adapter and Extension Cable), in which the Integra Camino Flex Adapter connects to the previously cleared Camino Advanced Monitor (510(k) K962928 Integra LifeSciences Corporation). The Integra Camino Flex Ventricular Intracranial Pressure Monitoring Kit with Integra Camino Flex Adapter is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required. The device is a single use, disposable product. The device is comprised of a highly flexible catheter with a tensile member, a pressure sensing tip, an electrical connection to a monitor, and a drainage lumen to allow fluid connection to an extraventricular drainage (EVD) device. The device is designed for the tunneling surgical method and the kit includes the necessary accessories for access and implantation of the catheter. The following Accessories are referenced in 510(k) K904883: Drill, Drill Stop, Set Screw, Hex Wrench, Trocar, Trocar Sheath, Suture Loops, and Male Luer Cap. The tip of the Integra Camino Flex Ventricular Catheter is implanted within the anterior horn of the left or right lateral cerebral ventricle. A cylindrical volume with a height of at least 11 mm and a diameter of at least 5 mm are required for catheter implantation. The Integra Camino Flex Adapter performs the functions of receiving the transducer signal from the Integra Camino Flex Ventricular Intracranial Pressure Monitoring Kit catheter, amplifying the signal, and transmitting the signal to the Camino® Advanced Monitor. The Integra Camino Flex Adapter converts the signals produced by the Integra Camino Flex Ventricular Intracranial Pressure Monitoring Kit catheter sensor. This signal is sent to the Adapter by means of the extension cable to the Camino® Advanced Monitor.
Sterilization Information	The Integra Camino Flex Ventricular Catheter Monitoring Kit (Catheter and Accessories) is sterilized by ethylene oxide. Testing was conducted with reference to AAMI TIR 28: 2009, ISO 11135-1:2007, ISO 10993-7:2008, ISO 11737-1:2006, ISO 11737-2:2009, USP <85>, and USP <161>. A half cycle sterilization cycle was

	run to confirm that the Integra Camino Flex Ventricular Intracranial Pressure Monitoring Kit could be adopted into the OSVII (flow regulating valve) family. Packaging integrity was conducted with reference to ISO 11607-1:2006, ASTM F1980-07:2011, ISTA 2A:2008, ASTM F2096-04, ASTM F88, and ASTM F1929-98:2004. The sterile kits are labeled as non-pyrogenic.
Intended use of the device	Use of the Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required.
Indications for use	Use of the Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
% Mr. Steven R. Peltier
Vice President Regulatory Affairs
311 Enterprise Drive
Plainsboro, NJ 08536

JUL 20 2012

Re: K121159
Trade Name: Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: Class II
Product Code: GWM
Dated: June 15, 2012
Received: June 18, 2012

Dear Mr. Peltier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121159

Integra LifeSciences Corporation-Traditional 510(k)

Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter

Indications for Use

510(k) Number (if known): K121159

Device Name:

Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter

Indications For Use:
The Integra™ Camino® Flex Ventricular Intracranial Pressure Monitoring Kit with Integra™ Camino® Flex Adapter is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121159